



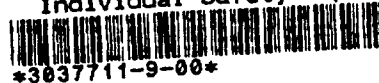
27-FEB-1998-0455

McN

McNEIL CONSUMER I  
FORT WASHING

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## Individual Safety Report



\*3037711-9-00\*

## A. Patient information

1. Patient identifier  Case #16  In confidence	2. Age at time of event: 51 yrs or Date of birth:	3. Sex (X) female ( ) male	4. Weight 143 lbs or kgs
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## B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)	( ) disability
(X) death (mo/day/yr) 12/14/94	( ) congenital anomaly
( ) life-threatening	( ) required intervention to prevent permanent impairment/damage
(X) hospitalization - initial or prolonged	( ) other:

3. Date of event (mo/day/yr) 11/27/94	4. Date of this report (mo/day/yr) 02/11/98
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## 5. Describe event or problem

Reports of 19 cases compiled by attorney & sent to FDA; Agency forwarded these reports to McNeil upon request to Docket No. 77N-094W, Ref. 94, Vol. 6 of 7. Of the 19 cases, 11 were previously submitted to FDA by McNeil (Mfr. # 0158783A, 0171537A, 0284020A, 0325998A, 0374114A, 0495613A, 0505064A, 0505223A, 0505252A, 0599479A, 0673820A). Case document #16 Death Summary indicates a 51yo F seen in ER (11/24/94) for mult. rib fx; she began taking TYLENOL & LORCET, 1-2 tablets q3h for pain & continuing to consume large amts of alcohol. On 11/27/97, pt seen in ER for NAUSEA, admitted & then transferred to 2nd hosp for HEPATIC FAILURE & (METRORRHAGIA) vaginal bleeding that spontaneously stopped. Pt's ILEUS improved for a while, developed progressive respiratory difficulty & shocked lung (RESPIRATORY DISORDER), intubated & placed on respirator. Pt became comatose (COMA), ceased responding. Respirator was tapered off & pt expired (DEATH) 12/14/94. Final Dx: Acute hepatic failure, secondary to combination of alcohol & acetaminophen, alcoholism, ileus, shock lung, HYPOKALEMIA & vaginal bleeding.

## 6. Relevant tests/laboratory data, including dates

11/27/94 SGOT=13000, Bili=27, ultrasound showed no ascites  
12/5/94 PT=13.7, PTT=27.1, WBC=21600, Hgb=11.5, Hct=33.6,  
Na=119, K= 4.2, NH3=46 12/6/94 SGPT=368, SGOT=75, Bili=23.7,  
AlkPhos=327, LDH=205 12/8/94 Hgb=9.1, Hct=26.9 (See Sect. 8.7)

## 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

significant for basically her heavy alcohol ingestion in the past; recent multiple rib fractures from her fall on 11/24/94; EXP LAP & bil. tubal ligation; allergic to sulfa & penicillin; (Cont' Sect. 8.6) 12/9/94 K=3.3, PLT=182K 12/10/94 urine & sputum culture=E.coli, CXR= showed diffused bil. infiltrates, c/w pneumonia, cardiac failure or shock lung

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 unknown TYLENOL product	
#2 LORCET®	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 1-2 tablets, q3hrs, po	#1 11/24/94-11/27/94; 4 days
#2 1-2 tablets, q3hrs, po	#2 11/24/94-11/27/94; 4 days
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 multiple rib fractures pain	#1 ( ) Yes (X) No ( ) N/A
#2 multiple rib fractures pain	#2 ( ) Yes (X) No ( ) N/A
6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2 n/a	#2 n/a
8. Event reappeared after reintroduction	
#1 ( ) Yes ( ) No (X) N/A	
#2 ( ) Yes ( ) No (X) N/A	
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event) OGEN®	

## G. All manufacturers

1. Contact office - name/address ( & mfring site for devices)	2. Phone number
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-233-7820
4. Date received by manufacturer (mo/day/yr) 12/31/97	3. Report source (check all that apply)
6. H IND protocol #	( ) foreign ( ) study ( ) literature ( ) consumer  ( ) health professional ( ) user facility ( ) company representative ( ) distributor (X) other: attorney
7. Type of report (check all that apply)	(A) NDA # 17-552 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes
8. Adverse event term(s)	
DEATH RESPIRATORY DIS ILEUS HYPOKALEMIA	LIVER FAILURE METRORRHAGIA COMA
9. Mfr. report number	
0932142A	

## E. Initial reporter

1. Name, address & phone #		
[Redacted]		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes (X) No	attorney	(X) Yes ( ) No ( ) Unk



Essential Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event